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| EXAMINER | |
|---|---|
| JAGOE, DONNA A | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/574,438 | NADESON ET AL. | |
| | Examiner | Art Unit | |
| | Donna Jagoe | 1619 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 August 2010 and 03 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on August 20, 2010 has been entered.

### *Claims 43-50 have been examined on the merits.*

Applicants' arguments filed August 20, 2010 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Response to Arguments*

Applicants' arguments filed September 3, 2010 have been fully considered but they are not persuasive. Applicants' assert that the references submitted provide evidence that unless appropriately diagnosed, neuropathic pain (NP) is not necessarily present in any given patient, such as the cancer patients of Nickel et al. Applicants'

paraphrase Dworkin et al. stating "[a]ppropriate diagnosis and assessment are *critical* to the successful treatment of NP". In response, Grond et al. teach that there are two types of pain, nociceptive and neuropathic.(page 16, column 1). Further, that neuropathic pain syndromes are one of the major problems of cancer pain treatment. Grond et al. teach employing an opioid analgesic (such as morphine) and non-opioid analgesics for the treatment of neuropathic pain stemming from cancer (see abstract and see table 1). Nickel et al. teach that flupirtine is a centrally acting analgesic (see introduction) and teach administration of flupirtine in combination with morphine for treatment of pain wherein it was demonstrated that the combination provided an increase in analgesic activity and furthermore flupirtine weakens morphine induced tolerance, physical dependence and behavior changes (see methods/results). It further states that flupirtine enhances the analgesic effects of opioids and this is confirmed in studies on cancer patients (see discussion). One skilled in the art, such as a pain management specialist, would have been motivated to employ the combination of flupirtine and an opioid, such as morphine, for treatment of cancer pain, such as neuropathic pain, motivated by the teaching of Grond et al. who teach that there both nociceptive and neuropathic pain treatment follow the same principals for cancer pain relief (page 16, column 1) and teach employing an opioid analgesic (such as morphine) and non-opioid analgesics for the treatment of neuropathic pain stemming from cancer (see abstract and see table 1). The artisan would be motivated to determine all operable and optimum conditions, including the treatment of neuropathic pain, such as

cancer pain comprising administering the combination of flupirtine and an opioid, such as morphine.

In the remarks dated August 20, 2010, Applicants' assert that the cited references fail to provide a reasonable expectation of success for methods of treating neuropathic pain and asserts that Nickel et al. do not even mention neuropathic pain and "at best, they suggest an enhanced effect for the combination of flupirtine and an opioid in treating nociceptive pain. In response, Applicants' exemplify cancer pain as the model for neuropathic pain. Nickel et al. teach that flupirtine enhances the analgesic effects of opioids and this is confirmed in studies on cancer patients (see discussion). The secondary reference, Grond et al., teach that neuropathic pain syndromes are one of the major problems of cancer pain treatment. Further, Grond et al. teach that both nociceptive and neuropathic pain treatment follow the same principals for cancer pain relief (page 16, column 1) and teach employing an opioid analgesic (such as morphine) and non-opioid analgesics for the treatment of neuropathic pain stemming from cancer (see abstract and see table 1). Applicants' state that the Bennet et al. and Kim et al. references teach that neuropathic pain differs from other types of pain. In response, Grond et al. teach that there are two types of pain, nociceptive and neuropathic and treatment follows the same principles (page 16, column 1 and table 1, page 16). Grond et al. further teach that the taxonomy of neuropathic pain syndromes is not uniform, as the concept of neuropathic, neurogenic, deafferentation, dyasthetic and non-nociceptive pain have been used often synonymously (page 18, column 2). Grond et al. further teach that the difference of the

mean pain intensity between nociceptive, mixed and neuropathic pain was not statistically significant and data cannot confirm the common belief that neuropathic pain is more severe than nociceptive pain (page 18, column 2).

Applicants' allege that an argument of inherency was relied on. In response, the rejection is one of obviousness, not anticipation. Applicants' introduces U.S. Patent 5,521,178 to Nickel et al. as evidence of non-obviousness because of "the conspicuous absence of any mention of neuropathic pain or even cancer pain in the '178 patent, combined with the use of animal models associated with nociceptive pain". Applicants' also asserts that the Nickel et al. '178 patent "casts doubt on the credibility" of the studies in cancer patients in the Nickel et al. that is relied upon in the rejection herein. Applicants' have provided no evidence other than speculation, so this assertion will not be addressed. As explained supra, it is recognized that Nickel et al. does not teach neuropathic pain per se. However, Nickel et al. teach treatment of cancer pain. Grond et al. teach, *inter alia*,

1. There are two types of pain, nociceptive and neuropathic;

2. Neuropathic pain syndromes are one of the major problems of cancer pain treatment (abstract); and

3. The difference of the mean pain intensity between nociceptive, mixed and neuropathic pain was not statistically significant and data cannot confirm the common belief that neuropathic pain is more severe than nociceptive pain (page 18, column 2).

Nickel et al. teach that flupirtine is a centrally acting analgesic (see introduction) and teach administration of flupirtine in combination with morphine for treatment of pain

wherein it was demonstrated that the combination provided an increase in analgesic activity and furthermore flupirtine weakens morphine induced tolerance, physical dependence and behavior changes (see methods/results). It further states that flupirtine enhances the analgesic effects of opioids and this is confirmed in studies on cancer patients (see discussion). One skilled in the art, such as a pain management specialist, would have been motivated to employ the combination of flupirtine and an opioid, such as morphine, for treatment of cancer pain, such as neuropathic pain, motivated by the teaching of Grond et al. who teach that there both nociceptive and neuropathic pain treatment follow the same principals for cancer pain relief (page 16, column 1) and teach employing an opioid analgesic (such as morphine) and non-opioid analgesics for the treatment of neuropathic pain stemming from cancer (see abstract and see table 1). The artisan would be motivated to determine all operable and optimum conditions, including the treatment of neuropathic pain, such as cancer pain comprising administering the combination of flupirtine and an opioid, such as morphine.

Applicants' assert that synergistic effects of the presently claimed subject matter are greater than expected from the art to an unobvious extent. In response, Nickel et al. teach that the combination of morphine and flupirtine provided an increase in analgesic activity and furthermore flupirtine weakens morphine induced tolerance, physical dependence and behavior changes (see methods/results) and flupirtine enhances the analgesic effects of opioids and this is confirmed in studies on cancer patients. Thus, Nickel et al. recognizes the same synergism. Applicants' state that there is no technical or mechanistic reason to expect these synergistic analgesic effects in the absence of

overt sedation and reasons that common sense suggests that when combining two agents with shared side effects, that one having ordinary skill in the art would expect a magnification of said side effects. In response, Nickel et al. teach flupirtine weakens morphine induced tolerance, physical dependence and behavior changes (see methods/results). Further, Grond et al. teach mostly non-opioid and opioid analgesics were used as a combination in all types of pain, including neuropathic pain stemming from cancer (page 17, column 2).

Addressing the references provided by Applicants' as proof that, for example, paracetamol/codeine has caused significantly higher proportion of side effects compared to each agent alone; this appears to be anecdotal evidence because these agents are well-known for treatment of pain when administered together and provides relief of pain by two different mechanisms. Codeine is a weak μ-opiate receptor agonist and the majority of its analgesic affect is due to metabolism to morphine. Opiate analgesia is mediated through changes in the perception of pain at the spinal cord and higher levels in the CNS. Opiate analgesics also alter the emotional response to pain. The stimulatory effects of opioids are the result of 'disinhibition' as the release of inhibitory neurotransmitters such as GABA and acetylcholine is blocked. Acetaminophen acts primarily in the CNS and increases the pain threshold by inhibiting cyclooxygenase, an enzyme involved in prostaglandin (PG) synthesis. Acetaminophen inhibits both isoforms of central cyclooxygenase, COX-1 and COX-2. Acetaminophen weakly inhibits PG synthesis in peripheral tissues, which is the reason for its lack of clinical useful peripheral anti-inflammatory effects. The antipyretic activity of

acetaminophen is exerted by blocking the effects of endogenous pyrogen on the hypothalamic heat-regulating center by inhibiting PG synthesis (see monograph at http://rx-s.net/weblog/more/acetaminophen-codeine/ ). Applicants' argue that Nickels et al. provide no technical reason to alter the expectation that the combination will cause side effects, such as sedation, somnolescence, nausea or similar-side effects. In reply, Nickels et al. teach flupirtine weakens morphine induced tolerance, physical dependence and behavior changes (see methods/results). Further, addressing side effects, such as sedation, Perovic et al. teach that flupirtine is a clinically safe compound with drowsiness reported in only 10% of cases (page 373, column 2). Since the dosage of the opioid is not disclosed, then the claim encompasses an almost negligible amount of opioid and as such overt sedation would not occur since it is dose related. Addressing arguments drawn to synergism, please refer to arguments answered supra on pages 6-7.

Applicants' are in disagreement with the Examiner's remarks drawn to the Declaration in the last office action wherein it was remarked that the references fail to show certain features of Applicants' invention, it is noted that the features upon which Applicants' rely (i.e., flupirtine in combination with an opioid allows a 90% reduction in the amount of either drug in order to obtain an analgesic effect for neuropathic pain) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants' state that the specification exemplifies the effect of this combination in a variety of models of

neuropathic pain under a variety of representative conditions and dosages and therefore correlate with the scope of the instant claim. In response, it is well established that the specification teaches an invention, whereas the claims define the **right to exclude**. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 [227 USPQ 577] n.14 (Fed. Cir. 1985).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites the limitation "the method of claim 49 wherein the cancer is selected from alopecia, ataxia-telangiectasia, Fanconi anaemia, histiocytosis, human papilomavirus, hydatidiform mole, hypercalcemia, Langerhans cell histiocytosis, Li-Fraumeni Syndrome, lymphedema, mycosis fungoides, nijmegen breakage syndrome, polycythemia vera, Rothmund-thomson syndrome, schwannoma and uroplakins. There is insufficient antecedent basis for these limitations in the claim because none of the above conditions are conditions are cancerous conditions.

The term "rare-cancers-and-associated-disorders" in claim 50 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus

one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how common a cancer can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "rare cancer", the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Further, the term "associated disorders" in claim 50 are not defined, rendering the claim indefinite because the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Where Applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the Applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "cancer" in claim 49 is used by the claim to mean "alopecia, ataxia-telangiectasia, Fanconi anaemia, histiocytosis, human papilomavirus, hydatidiform mole, hypercalcemia, Langerhans cell histiocytosis, Li-Fraumeni Syndrome, lymphedema, mycosis fungoides, nijmegen breakage syndrome, polycythemia vera, Rothmund-thomson syndrome, schwannoma and uroplakins", while the accepted meaning is "General term frequently used to indicate any of various types of malignant neoplasms, most of which invade surrounding tissues, may metastasize to several sites." The term is indefinite because the specification does not clearly redefine

the term. None of the above recited maladies fall within the well-known definition of cancer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants' are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-45, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nickel et al. (U) Regional Anesthesia and Pain Medicine: July/August, 1993, Vol. 18 No. 4 Page 4) and Grond et al. (V) (Pain, 79 1999 15-20)

Nickel et al. teach that flupirtine is a centrally acting analgesic (see introduction) and teach administration of flupirtine in combination with morphine for treatment of pain wherein it was demonstrated that the combination provided an increase in analgesic activity and furthermore flupirtine weakens morphine induced tolerance, physical dependence and behavior changes (see methods/results). It further states that flupirtine enhances the analgesic effects of opioids and this is confirmed in studies on cancer patients (see discussion).

Nickel et al. does not teach specifically treatment of neuropathic pain.

Grond et al. teach that there are two types of pain; nociceptive and neuropathic (page 16, column 1). Further, that neuropathic pain syndromes are one of the major problems of cancer pain treatment. Grond et al. teach employing an opioid analgesic (such as morphine) and non-opioid analgesics for the treatment of neuropathic pain stemming from cancer (see abstract and see table 1).

Grond et al. does not teach administration of flupirtine.

It would have been obvious to employ the combination of flupirtine and an opioid analgesic, such as morphine for the treatment of neuropathic pain, especially from cancer pain, motivated by the teaching of Nickel et al. who teach that flupirtine is a

centrally acting analgesic (see introduction) that enhances the analgesic effects of opioids, such as morphine for treatment of cancer pain, and the teaching of Grond et al. who teach that neuropathic pain syndromes are one of the major problems of cancer pain treatment and teach that opioids are often combined with non-opioid agents in the treatment of cancer pain. One skilled in the art, such as a pain management specialist, would have been motivated to employ the combination of flupirtine and an opioid, such as morphine, for treatment of cancer pain, such as neuropathic pain, motivated by the teaching of Grond et al. who teach that there both nociceptive and neuropathic pain treatment follow the same principals for cancer pain relief (page 16, column 1) and teach employing an opioid analgesic (such as morphine) and non-opioid analgesics for the treatment of neuropathic pain stemming from cancer (see abstract and see table 1). The artisan would be motivated to determine all operable and optimum conditions, including the treatment of neuropathic pain, such as cancer pain comprising administering the combination of flupirtine and an opioid, such as morphine.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nickel et al. (Regional Anesthesia and Pain Medicine: July/August, 1993, Vol. 18 No. 4 Page 4) and Grond et al. (Pain, 79 1999) as applied to claims 43-45, 48 and 49 above, and further in view of Perovic et al (Neurodegeneration, Vol. 4 pages 369-374 (1995)).

Perovic et al. teach that flupirtine is a clinically safe compound with drowsiness reported in only 10% of cases (page 373, column 2). Since the dosage of the opioid is

not disclosed, then the claim encompasses an almost negligible amount of opioid and as such overt sedation would not occur since it is dose related.

It would have been made obvious to one of ordinary skill in art at the time it was made to employ a non sedating combination of flupirtine and an opioid motivated by the teaching of Perovic et al. that flupirtine caused drowsiness in only 10 % of cases combined with the well known fact that sedation of opioid analgesics is dose related and since the claims do not disclose the dosage, they encompass a negligible amount of opioid. Further, Nickel et al. teach that flupirtine weakens morphine induced behavior changes (see methods/results). One having ordinary skill in the art at the time the invention was made would reasonably deduce that sedation is one of the primary behavior changes that morphine induces.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nickel et al. (U) Regional Anesthesia and Pain Medicine: July/August, 1993, Vol. 18 No. 4 Page 4) and Grond et al. (V) (Pain, 79 1999) as applied to claims 43-45, 48 and 49 above, and further in view of Devulder at al. (U).

Devulder et al. teach the dose of flupirtine for treatment of neuropathic (central) pain is 300-600 mg/day. The instant claim is drawn to 0.5mg/kg to about 20 mg/kg of body weight. Translating the dose of Devulder et al. to mg/kg based on an average 80 kg human the dosage would be 3.75 mg/kg[1] to 7.5 mg/kg[2]. This dosage amount is

[1] 300 mg / 80 kg = 3.75 mg/kg
[2] 600 mg / 80 kg = 7.5 mg/kg

encompassed by the claimed amount of 0.5 mg/kg to about 20 mg/kg. A prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). See also *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005).

It would have been made obvious to one of ordinary skill in art at the time it was made to employ 0.5 mg/kg to about 20 mg/kg of flupirtine in the composition combined with another opioid agent, such as morphine to treat neuropathic pain motivated by the teaching of Nickel et al. and Grond et al (supra) and the teaching of Devulder et al. who teaches that the dosage of flupirtine for central (neuropathic) pain is 300 to 600 mg/day (approximately 3.75 mg/kg to about 7.5 mg/kg).

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nickel et al. (U) Regional Anesthesia and Pain Medicine: July/August, 1993, Vol. 18 No. 4 Page 4) and Grond et al. (V) (Pain, 79 1999) as applied to claims 43-45, 48 and 49 above, and further in view of Cleary (Cancer Control, 2000 ).

Cleary teaches that cancer pain can have a neuropathic component (page 122, column 2 "character"). It further identifies specific cancers for which such neuropathies occur, such as colon cancer, non-small cell lung cancer and multi-organ system failure associated with cancer (page 121, column 2 bridging to page 122). Cleary also discloses that although opioids are the mainstay of cancer pain management, adjunct therapy is recommended. Adjuvant medications may result in a decrease in opioid dose

with an associated decrease in side effects and adjuvant therapy is often useful with opioids in the treatment of neuropathic pain. (page 127, column 2).

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1619

November 2, 2010

/Andrew D Kosar/
Primary Examiner, Art Unit 1654